Paper 44

Filed: August 29, 2011

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GARY S. **ROUBIN**, GEOFFREY HAMILTON WHITE, SRIRAM S. IYER, RUSSELL J. REDMOND, and CLAUDE A. VIDAL Junior Party (Patent Nos. 5,827,321, 6,475,236 and 6,106,548)¹

V.

PAUL H. **BURMEISTER**, CHARLES L. EUTENEUER, BRIAN J. BROWN, PAUL J. FORDENBACHER, and ANTHONY C. VRBA Senior Party (Application 09/427,291)²

Patent Interference No. 105,794 (Technology Center 3700)

Before: JAMESON LEE, SALLY GARDNER LANE and SALLY C. MEDLEY, *Administrative Patent Judges*.

LEE, Administrative Patent Judge.

1

Judgment – Merits – Bd. R. 127

1 The real party in interest is Endosystems, LLC.

2 The real party in interest is Boston Scientific Scimed, Inc.

| 1 | Junior party Roubin has not filed a preliminary statement. Junior party |
|----------|---|
| 2 | Roubin has not attacked the accorded benefit dates of Senior Party Burmeister. |
| 3 | Junior party has indicated that it will not be filing a priority motion. Junior party |
| 4 | Roubin recognizes that it has in essence conceded priority. (Paper 26). |
| 5 | In a separate concurrent paper, we have denied junior party Roubin's Motion |
| 6 | 1 to designate certain claims as not corresponding to the count. No other motion is |
| 7 | pending before the Board. Time is now appropriate to enter judgment against the |
| 8 | junior party. It is |
| 9 | ORDERED that judgment as to the subject matter of Count 1 is herein |
| 10 | entered against junior party GARY S. ROUBIN, GEOFFREY HAMILTON |
| 11 | WHITE, SRIRAM S. IYER, RUSSEL J. REDMOND, and CLAUDE A. VIDAL; |
| 12 | FURTHER ORDERED that junior party GARY S. ROUBIN, GEOFFREY |
| 13 | HAMILTON WHITE, SRIRAM S. IYER, RUSSEL J. REDMOND, and CLAUDE |
| 14 | A. VIDAL is not entitled to claims 1-54 of Patent 5,827,321, claims 1-25 of Patent |
| 15 | 6,475,236, and claims 1-12 of Patent 6,106,548, which correspond to Count 1; |
| 16 | FURTHER ORDERED that claims 1-54 of Patent 5,827,321, claims 1-25 |
| 17 | of Patent 6,475,236, and claims 1-12 of Patent 6,106,548 are herein cancelled; |
| 18 | EUDTHER OPPERED 1 1'C1 ' 11 ' 11 ' 11 ' 11 ' 11 |
| | FURTHER ORDERED that if there is a settlement agreement, the parties |
| 19 | should note the requirements of 35 U.S.C. § 135(c) and 37 CFR § 1.666; and |
| 19 20 | • |
| | should note the requirements of 35 U.S.C. § 135(c) and 37 CFR § 1.666; and |

By Electronic Transmission:

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Paper 43

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

GARY S. **ROUBIN**, GEOFFREY HAMILTON WHITE, SRIRAM S. IYER, RUSSELL J. REDMOND, and CLAUDE A. VIDAL Junior Party (Patent Nos. 5,827,321, 6,475,236 and 6,106,548)

v.

PAUL H. **BURMEISTER**, CHARLES L. EUTENEUER, BRIAN J. BROWN, PAUL J. FORDENBACHER, and ANTHONY C. VRBA Senior Party (Application 09/427,291)

Patent Interference No. 105,794 (JL) (Technology Center 3700)

Before LEE, LANE, and MEDLEY, Administrative Patent Judges.

LEE, Administrative Patent Judge.

Decision -- Motions -- Bd. R. 125(a)

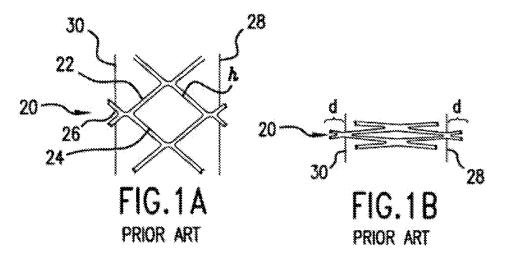
- 1 This interference was declared on February 7, 2011. The sole authorized
- 2 motion is Roubin's Motion 1 which seeks to designate the following claims of
- 3 Roubin's involved patents as not corresponding to the count:

| 1 | | Patent 5,827,321: claims 8, 10-12, 16-19, and 21-54 |
|----------------------------------|-------|--|
| 2 | | Patent 6,475,236: claims 1-25 |
| 3 | | Patent 6,106,548: claims 1-12 |
| 4 | | Burmeister filed no opposition to Roubin's Motion 1. Nevertheless, for |
| 5 | failu | re to meet Roubin's applicable burden of proof, Roubin's Motion 1 is denied. |
| 6 | | Findings of Fact |
| 7 | 1. | Junior party Roubin is involved in this interference on the basis of three |
| 8 | pater | ts: Patent 5,827,321 (Roubin '321); Patent 6,475,236 (Roubin '236); and |
| 9 | Pater | at 6,106,548 (Roubin '548). |
| 10 | 2. | Senior party Burmeister is involved in this interference on the basis of |
| 11 | Appl | ication 09/427,291, filed October 26, 1999. |
| 12 | 3. | Roubin's real party in interest is Endosystems, LLC. |
| 13 | 4. | Burmeister's real party in interest is Boston Scientific Scimed, Inc. |
| 14 | 5. | The sole count in this interference is Count 1, which is defined as: |
| 15 | | Claim 1 of Roubin's Patent 5,827,321 |
| 16 | | or |
| 17 | | Claim 22 of Burmeister's Application 09/427,291 |
| 18 | 6. | Claim 1 of Roubin's Patent 5,827,321 reads as follows: |
| 19 | | 1. A stent comprising: |
| 20 21 22 23 24 25 | | a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and |
| 26 | | connecting members connecting adjacent annular elements; |

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

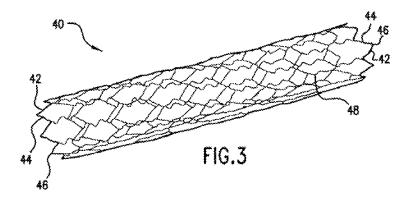
Roubin '321

7. According to Roubin '321, the effectiveness of pre-existing stent designs is critically affected by proper placement within a body vessel, and positioning is affected by the change in the stents' longitudinal length from the compressed to the expanded state due to foreshortening of the stent members. (Roubin '321 1:32-52). A foreshortening prior art stent, as illustrated by Figs. 1A and 1B from Roubin '321, is depicted below:

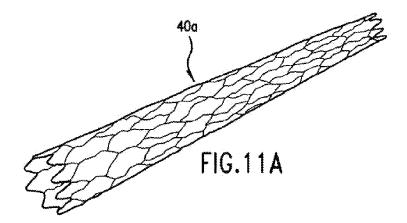


8. The Specification of Roubin '321 also identifies that positioning within a body vessel is not only affected by foreshortening, but may also be affected by unique vessel shapes as certain body vessels experience a change in vessel lumen diameter due to anatomy or disease. (Roubin '321 2:6-56).

- 1 9. Roubin '321 discloses an expandable stent, and an expandable stent with a
- 2 tapered diameter, illustrated respectively in Figures 3 and 11A, reproduced
- 3 below:



4

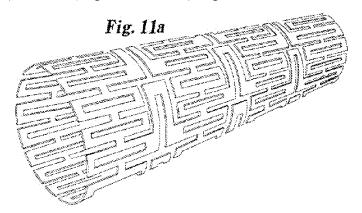


- 6 10. In Roubin '321 the preferred embodiment of a non-foreshortening
- 7 intraluminal stent is made up of a plurality of annular elements and connecting
- 8 members, wherein the connecting members vary in length to compensate for the
- 9 foreshortening of the annular elements. (Roubin '321 2:66-3:16).
- 10 11. Roubin's Motion 1 discusses the following references as applicable prior
- art: Burmeister's WO 95/31945 publication (Burmeister WO); Jang's Patent

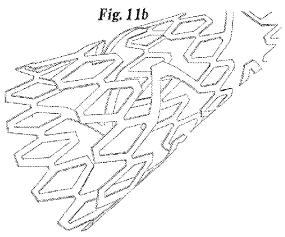
- 1 5,954,743 (Jang '743); Goicoechea's Patent 5,609,627 (Goicoechea
- 2 '627); and Fischell's Patent 5,749,825 (Fischell '825).

3 Burmeister WO

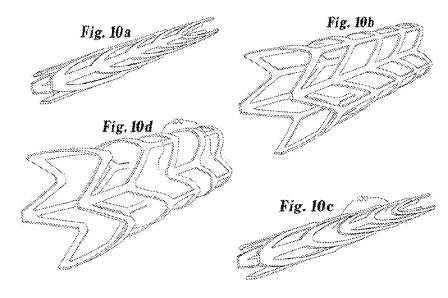
- 4 12. Burmeister WO discloses an expandable stent having annular elements
- 5 with connecting members that compensate for the foreshortening of expanded
- 6 annular elements (Burmeister WO 12:11-25), as illustrated in Figures 11a
- 7 (compressed state) & 11b (expanded state) reproduced below:



8



- 10 13. Burmeister WO discloses improving flexibility by omitting connecting
- members. Omitted connecting members 100 are labeled in Figures 10a and 10b,
- depicted below. (Burmeister WO 12:11-25).



- 1
- 2 14. Burmeister WO discloses stents having open and closed configurations.
- 3 With an open configuration corresponding to a stent with omitted connecting
- 4 members, and a closed configuration corresponding to a stent with all connecting
- 5 members. Figures 10a and 10b, depicted above, represent stents in a closed
- 6 configuration, and figures 10c and 10d, depicted above, represent stents in an
- 7 open configuration. (Burmeister WO 12:11-25).
- 8 15. Burmeister WO discloses expandable stents having spaces between alternating
- 9 struts that form a spiral pattern. Figures 8a and 8b are illustrated below:

Fig. 8a

Fig. 8b

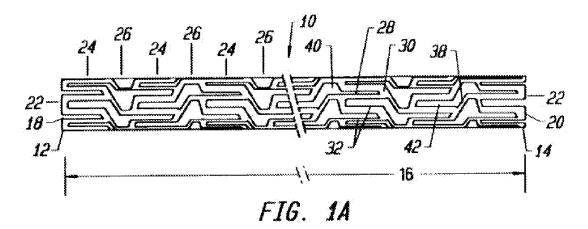
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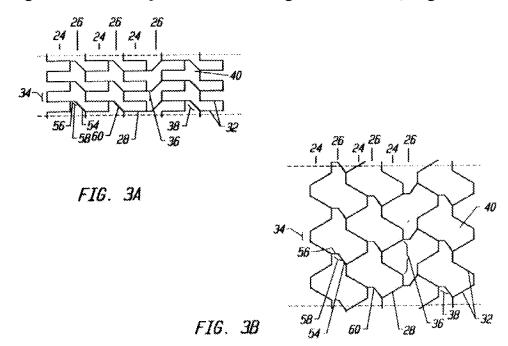
<u>Jang '743</u>

Jang '743 discloses an expandable stent having expansion struts 28,
connecting struts 38, and joining struts 30, (Jang '743 4:66-5:54), as shown in
Fig. 1A.



- Jang '743 discloses an expandable stent that has substantially constant
 unexpanded and expanded longitudinal lengths. (Jang '743 7:52-54).
- 10 18. Jang '743 discloses an expandable stent wherein the foreshortening of struts 28 during expansion is countered by the longitudinal lengthening of

1 connecting struts 38, as depicted below in Figs. 3A and 3B (Jang '743 7:42-54):



- 3 19. Also, Jang '743 discloses several ways to achieve a tapered expanded
- 4 stent, one of which involves removing progressively larger portions of the
- 5 expansion struts 28 to remove corresponding ones of segments 72, 74, 76,
- 6 78, 80, 82, and 84 shown in Figure 5 (Jang '743 9:9-10:38):

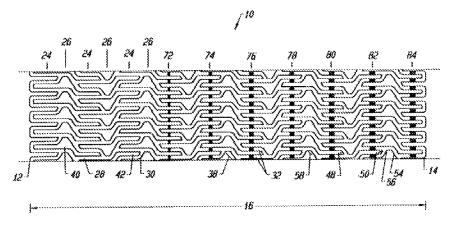
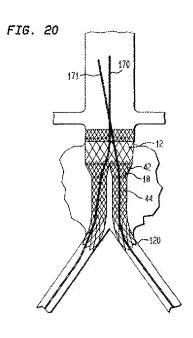


FIG. 5

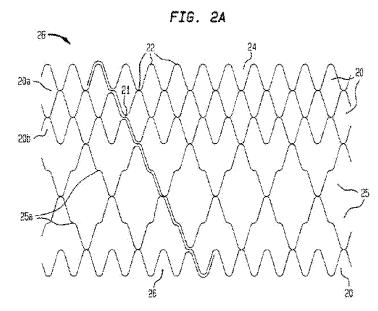
Goicoechea '627

- 2 20. Goicoechea '627 discloses a bifurcated stent that has segments with
- 3 different diameters (12, 44) and segments that are tapered (14, 18). (Goicoechea
- 4 '627 8:50-63). See Fig. 20 depicted below:



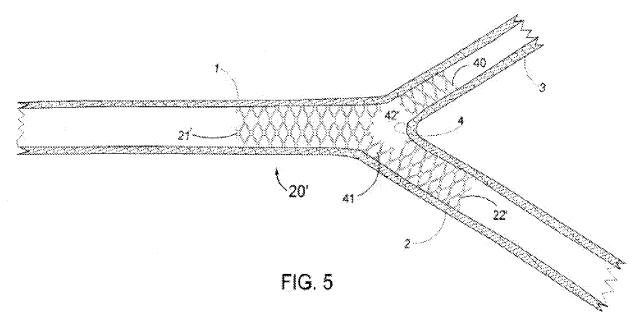
5

- 6 21. Goicoechea '627 discloses a stent made of Nitinol having a plurality of single
- 7 hoops 20 of unit width and intermediate hoops 25 of twice unit width, which are
- 8 connected by securing means made of Nitinol elements or polypropylene filaments.
- 9 (Goicoechea '627 9:1-61). See Fig. 2A reproduced below:



- 2 22. Goicoechea '627 discloses a stent with intermediate hoops 25 having a
- 3 plurality of offsets 25a that are created when Nitinol wire is wound around pins
- 4 instead of creating single hoops 20. (*Id.*).
- 5 23. Intermediate hoops 25 are formed by omitting single hoops 20, which leave
- 6 apices 22 unconnected where the stent transitions from intermediate hoops 25 to
- 7 single hoops 20. (*Id.*).

- 8 24. Intermediate hoops 25 are the size of four single hoops 20, and formed by
- 9 omitting two single hoops 20 connected at their apices 22. (*Id.*).
- 10 <u>Fischell '825</u>
- 11 25. Fischell '825 discloses dual diameter stents to accommodate a non-uniform
- diameter vessel (Fischell '825 5:31-46), as illustrated in Fig. 5 reproduced below:



26. Fischell '825 teaches creating an opening to allow unobstructed blood flow by not connecting alternating struts and apices. (Fischell '825 1:43-67; 4:31-41).

Analysis

Roubin's Motion 1 seeks to designate claims 8, 10-12, 16-19, and 21-54 of Roubin '321, claims 1-25 of Roubin '236, and claims 1-12 of Roubin '548 as not corresponding to the count. Roubin as the moving party bears the burden of proof to establish entitlement to the relief requested. 37 C.F.R. § 41.121(b). A claim corresponds to a count if the subject matter of the count, treated as prior art to the claim, would have anticipated or rendered obvious the subject matter of the claim. 37 C.F.R. § 41.207(b)(2).

It is evident that the count, if treated as prior art, would not have anticipated any of the Roubin claims which the motion seeks to designate as not corresponding to the count. Thus, the proper analysis is one of obviousness per *Graham v. John Deer Co.*, 383 U.S. 1 (1966). The pertinent factual inquiries are

(1) the scope and content of the prior art, (2) the differences between the claimed 1 2 invention and the prior art, (3) the level of ordinary skill in the art, and (4) any 3 objective evidence of nonobviousness. *Id.* at 17. One cannot show non-4 obviousness by attacking references individually where the rejections are based 5 on combinations of references. *In re Keller*, 642 F.2d 413, 426 (CCPA 1981). Also, a person of ordinary skill in the art has ordinary creativity and is not 6 an automaton. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007). If a 7 8 technique has been used to improve one device, and a person of ordinary skill in 9 the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her 10 skill. KSR Int'l Co., 550 U.S at 417. 11 Roubin has to demonstrate by a preponderance of the evidence that each of 12 the claims it seeks to designate as not corresponding to the count would not have 13 been obvious to one with ordinary skill in the art, given the subject matter of the 14 count as prior art and any other applicable prior art. In that regard, Roubin 15 identifies many differences between the claims and the count. 16 17 For all of the reasons discussed below, Roubin has not satisfied its burden of proof that the collective differences between each claim it seeks to designate as 18 not corresponding to the count and the subject matter of the count are such that 19 the claim would not have been obvious over the count. 20 At the outset, it is noted that the Board had given notice to Roubin that it 21 22 may not in its motion to designate claims as not corresponding to the count 23 restrict its analysis to only the prior art of record in either party's involved 24 application or patent but must address the level of ordinary skill in the art as well

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as that prior art otherwise known to Roubin. (Paper 26). In its Motion 1, Roubin 1 2 discusses only the prior art of record and makes no representation that it is 3 unaware of any prior art which discloses the various features it alleges is missing 4 from the subject matter of the count. It cannot be assumed that the prior art of 5 record is the closest prior art for the features identified by Roubin as not present within the count or that Roubin is not aware of other prior art disclosing such 6 7 features. For that reason alone, Roubin's Motion 1 motion is inadequate. Additional deficiencies of Roubin's Motion 1 are discussed below. 8 A. 9 Varying Diameter in the Expanded State 10 For claims 16-18, 23-25, and 51-53 of Patent 5,827,321, claims 1-25 of Patent 6,475,236, and claims 3, 4, and 8-12 of Patent 6,106,548, Roubin correctly 11 points out that each claim requires a stent in the expanded state having two or 12 13 more segments along its length, with each segment assuming a different diameter 14 in the expanded state. The count has no such requirement and we refer to it as the 15 varying-diameter feature. With regard to the varying diameter feature, Roubin specifically discusses 16 17 four prior art references identified in the prosecution history of Burmeister's 18 involved application and asserts that none makes up for the missing varyingdiameter feature: (1) Burmeister WO, (2) Jang '743, (3) Goicoechea '627, and 19 (4) Fischell '825. 20 With regard to Burmeister WO, we agree with Roubin that it does not 21 22 disclose a stent having multiple segments with different diameters. It neither 23 teaches nor suggests the varying-diameter feature. With regard to the other three

prior art references in combination with the subject matter of the count as prior

1 art, however, Roubin's arguments are misplaced.

Roubin asserts merely that implementing the varying-diameter feature disclosed in each of Jang '743, Goicoechea '627, and Fischell '825 within the subject matter of the count raises design considerations for one with ordinary skill and makes it more difficult than it would be otherwise. But Roubin nowhere asserts and the evidence does not support that implementing the varying-diameter feature within the subject matter of the count would have been beyond the skill of one with ordinary skill. Note that the subject matter of the count is treated as prior art and Roubin acknowledges Jang '743, Goicoechea '627, and Fischell '825 as prior art.

Each of Jang '743, Fischell '825, and Goicoechea '627 discloses a stent including the varying-diameter feature. It would have been at least prima facie obvious to one with ordinary skill in the art to include such a known feature into a stent according to the count treated as prior art. Roubin can rebut the prima facie case of obviousness by making a showing that the combination would have been so technically complex that it could not have been accomplished by one with ordinary skill in the art and that one with ordinary skill in the art would not have expected to successfully complete the combination. However, Roubin makes no such assertion, much less submit evidence sufficient to demonstrate the same.

That implementing the varying-diameter feature of Jang '743, Goicoechea '627, or Fischell '825 in the subject matter of the count would involve design considerations is certainly expected. That should be the beginning of Roubin's analysis, not the end. A person of ordinary skill in the art is presumed to have skills apart from what the prior art references explicitly say. *KSR Int'l Co.*, 550

- U.S. at 418. One with ordinary skill in the art is a person of ordinary creativity 1 2 and is not an automaton. *Id.* at 421. Roubin has not asserted, much less established, that the task of implementing the varying-diameter feature in 3 4 combination with the subject matter of the count would have been beyond the level of ordinary skill in the art to accomplish and could not have been achieved 5 by one with ordinary skill in the art. Stopping short at stating that there will be 6 design considerations to contemplate seriously undermines Roubin's analysis. 7 8 Moreover, Jang'743 discloses expansion and connecting struts that 9 correspond to the count's annular elements and connecting members, (Jang '743 7:32-8:12). Jang '743 also discloses various methods to vary the diameter of 10 11 different segments of an expanded stent, which include changing the stiffness of struts, using a tapered balloon to expand a non-tapered stent, employing 12 13 reinforced expansion struts; and removing portions of the expansion struts. (Jang 14 '743 9:10 to 10:38). One with ordinary skill in the art would have known to include in its implementation effort at least the various methods disclosed in Jang 15 '743 which reflect the level of ordinary skill in the art. 16 Same Aperture Geometry/Different Aperture Size 17 В. For claims 21-32 of Patent 5,827,321, Roubin correctly points out that each 18 claim recites a stent with a first and a second segment wherein the apertures of the 19 first and second segments have different sizes but "substantially the same 20 geometric configuration" when the first and second segments are in the expanded 21 22 state. The count has no such requirement and we refer to it as the substantiallythe-same-geometry feature. 23
 - Based on that feature, Roubin seeks to designate claims 21-32 of Roubin

'321 as not corresponding to the count. In its argument, Roubin specifically 1 2 discusses Goicoechea '627, and asserts that it does not disclose apertures that have different sizes but substantially the same geometric configuration in the 3 expanded state. We disagree. 4 Goicoechea '627 discloses apertures of different sizes but substantially the 5 same geometry as depicted in Fig. 2A shown above. Hoops 20 and 25 have 6 7 substantially the same geometric shape while hoop 20 has a unit width of one and hoop 25 has a unit width of two. (Goicoechea '627 9:20-61). Hoops 20 and 25 8 9 are connected by securing means of Nitinol loops, creating annular elements 10 connected by connecting members. (*Id.*). 11 While it is true that large hoops 25 have perimeters which include a small slightly undulating portion on each side due to the particular manner of 12 13 construction and the small hoops 20 do not, it cannot be reasonably disputed that the overall contours of the small and large hoops are "substantially the same." 14 The substantially-the-same geometry feature requires not identity of configuration 15 16 but only substantial sameness. Roubin gives no satisfactory explanation on why the shapes of hoops 20 and 25 are not "substantially the same" as is claimed. 17 Even if the shapes of hoops 20 and 25 are considered not to be substantially 18 the same, it is not explained why one with ordinary skill in the art would not have 19 20 recognized from the disclosure of Goicoechea '627 that the contours of hoops 20 21 and 25 can be made substantially the same. In particular, Roubin cites no portion 22 of Goicoechea '627 which indicates that larger hoops 25 must be made with the small slightly undulating portion on each side. 23

| 1 | Roubin further argues that the apertures shown in Goicoechea '627 are not |
|----|---|
| 2 | of the same type as the ones recited in the count because in Goicoechea there are |
| 3 | no connecting members connecting adjacent annular elements. The argument is |
| 4 | without merit. The annular elements in Goicoechea '627 are the hoops 20 and 25, |
| 5 | and adjacent members of the hoops are connected in a number of different ways |
| 6 | such as Nitinol loops, rings, or staples. (Goicoechea '627 9:53-61). Roubin's |
| 7 | argument is also misplaced because one cannot show non-obviousness by |
| 8 | attacking references individually where the issue involves a combination of |
| 9 | references. In re Keller, 642 F.2d 413, 426(CCPA 1981). Here, the count itself is |
| 10 | treated as prior art and Roubin does not adequately explain why the hoops of |
| 11 | Goicoechea cannot be connected as recited in the count. |
| 12 | C. Annular Element in an Open Configuration |
| 13 | For claims 8, 32, and 38-58 of Roubin '321, Roubin correctly points out |
| 14 | each claim requires a stent having at least one annular element in an open |
| 15 | configuration, i.e., that the plurality of alternating struts and apices which define |
| 16 | an annular element are not connected in at least one location. (Motion 11:4-8). |
| 17 | The count has no such requirement and we refer to it as the open-element feature. |
| 18 | Roubin argues that based on the open-element feature alone, the claims |
| 19 | would not have been obvious to one having ordinary skill in the art over the |
| 20 | count. (Id. 13:13-19). Roubin discusses three references identified in the |
| 21 | prosecution history of Burmeister's involved application and asserts that none |
| 22 | makes up for the identified difference between the claims and the count treated as |
| 23 | prior art: (1) Burmeister WO, (2) Goicoechea '627, and (3) Fischell '825. |
| 24 | Roubin asserts that each of the references, individually, does not teach the open- |

24

element feature as required by the claims. The argument is misplaced 1 2 Roubin cannot show non-obviousness by attacking references individually where the issue is based on a combination of prior art. See In re Keller, 642 F.2d 3 4 at 426. It cannot be ignored that the count is also treated as prior art. Also, a person of ordinary skill is presumed to have skills apart from what the references 5 explicitly say. KSR Int'l Co., 550 U.S. at 418. One with ordinary skill is also a 6 7 person of ordinary creativity and is not an automaton. *Id.* at 421. 8 Roubin acknowledges that Burmeister WO discloses omitting connecting 9 members to render a stent flexible for articulation. (Motion 11:29-12:1). Roubin 10 also acknowledges that Fischell '825 shows a stent with a plurality of integrally 11 connected struts which define annular elements with an open portion 42' between portions of the stent 21', 22'. (Id. 12:29-13:6). Roubin does not adequately 12 13 explain why one with ordinary skill would not have known, in light of Burmeister 14 WO or Fischell '825, to omit in the subject matter of the count a connecting member or a portion of a stent thus satisfying the open-element feature. 15 Furthermore, Goicoechea '627 discloses an expandable stent having 16 17 intermediate hoops created by omitting an annular element, e.g., a single hoop, leaving unconnected apices in an open configuration. (Goicoechea '627 9:20-33). 18 19 Roubin has not adequately explained why one with ordinary skill would not have 20 known, in light of Goicoechea '627, to omit in the subject matter of the count all 21 or a portion of an annular element thus leaving at least one annular element 22 unconnected at one location thus satisfying the open-element feature. 23

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D. Gaps by Omitting Struts 1 2 For claims 35-37 of Patent 5,827,321, Roubin correctly points out that each of these claims recites a stent having a plurality of gaps formed by omitting at 3 4 least one of the struts. The count has no such requirement and we refer to it as the gap feature. 5 Roubin specifically discusses three prior art references: (1) Burmeister 6 WO, (2) Fischell '825, and (3) Goicoechea '627. Roubin alleges that none of the 7 three references teaches including the gap feature in subject matter of the count. 8 The argument is misplaced. 9 10 Roubin cannot show non-obviousness by attacking references individually 11 where the issue is based on a combination of prior art. In re Keller, 642 F.2d at 426. Here, it cannot be ignored that the count is also treated as prior art. Also, a 12 person of ordinary skill in the art is presumed to have skills apart from what the 13 prior art references explicitly say. KSR Int'l Co., 550 U.S. at 418. One with 14 ordinary skill in the art is also a person of ordinary creativity and is not an 15 automaton. Id. at 421. 16 While Burmeister WO does not suggest removing a strut, Roubin 17 acknowledges that Burmeister WO discloses omitting connecting members to 18 19 render a stent flexible. (Motion 11:29-12:1). Burmeister WO discloses omitting 20 connecting members to create a gap. (Burmeister WO 12:11-16). Fischell '825's 21 Figure 5 discloses a gap in the expandable stent by omitting struts. (Fischell '825 22 4:31-41). Goicoechea '627 discloses offsets created by omitting a hoop to form a gap. (Goicoechea '627 9:20-33). Thus, each of Burmeister WO, Fischell '825, 23

and Goicoechea '627 discloses a stent including the gap feature.

| 1 | Roubin has not adequately explained why in light of Burmeister WO, |
|----|---|
| 2 | Fischell '825, and Goicoechea '627, one with ordinary skill in the art would not |
| 3 | have known to form the gap feature within the subject matter of the count. |
| 4 | E. Consistent Length between Expanded and Compressed States |
| 5 | For claim 7 of Patent 6,475,236, Roubin correctly points out that the claim |
| 6 | recites a stent wherein the length is consistently maintained throughout expansion |
| 7 | of the stent from the compressed state. The count has no such requirement and |
| 8 | we refer to it as the consistent-length feature. |
| 9 | Roubin argues that one of ordinary skill in the art would not have expected |
| 10 | that a stent according to the count would necessarily consistently maintain the |
| 11 | length of the stent from the compressed to the expanded state. (Motion 15:11- |
| 12 | 15). The argument is misplaced. The issue is not whether a stent according to the |
| 13 | count would necessarily include the consistent-length feature, but whether the |
| 14 | consistent-length feature would have been obvious to one with ordinary skill |
| 15 | when the count is treated as prior art. |
| 16 | Roubin further argues that even if Jang '743 did teach a stent with reduced |
| 17 | foreshortening, the design would not have suggested the consistent-length feature |
| 18 | (Id. 15:27-32). The argument lacks underlying analysis and is unpersuasive. |
| 19 | Jang '743 teaches an expandable stent that has a substantially constant |
| 20 | unexpanded and expanded longitudinal length to help alleviate the foreshortening |
| 21 | of a stent from the compressed to the expanded state. (Jang '743 7:42-54; 9:10- |
| 22 | 65). It would have been at least prima facie obvious to one with ordinary skill in |
| 23 | the art that if the stent in its compressed and expanded states has substantially the |
| 24 | same length, then it likely has substantially the same length during the transition |

from the compressed to the expanded state. Moreover, Jang '743 does not 1 2 disclose a substantially different stent length during the transition. That implementing the consistent-length feature of Jang '743 in the subject matter of 3 4 the count would involve design considerations is expected. That should be the beginning of Roubin's analysis and not the end. A person of ordinary skill in the 5 art is presumed to have skills apart from what the prior art references explicitly 6 say. KSR Int'l Co. 550 U.S. at 418. One with ordinary skill in the art is also a 7 8 person of ordinary creativity and is not an automaton. *Id.* at 421. Roubin has not asserted, much less established, that the task of implementing the consistent-9 10 length feature in combination with the count would have been beyond the level of ordinary skill in the art to accomplish and could not have been achieved by one 11 with ordinary skill in the art. 12 13 F. Spiral Pattern of Omitted Connecting Members or Struts Claim 34 refers to omitting connecting members of an expandable stent 14 with a plurality of segments, with the omitted connecting members forming a 15 spiral pattern on the stent. Claim 37 similarly refers to omitting struts of the stent, 16 with the omitted struts forming a spiral pattern on the stent. We refer to the 17 limitation in claim 34 and the limitation in claim 37 as the spiral-pattern-omission 18 19 feature. With regard to the spiral pattern feature, Roubin specifically discusses only 20 Burmeister WO and Goicoechea '627. We agree with Roubin that the subject 21 22 matter of the count in combination with either Burmeister WO or Goicoechea '627 would not have reasonably suggested the spiral-pattern-omission feature. 23 However, Roubin still has not met its burden of proof by a preponderance 24

| 1 | of the evidence. The hypothetical person of ordinary skill in the art is not aware |
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| 2 | of not just Burmeister WO and Goicoechea '627. We recognize that Roubin |
| 3 | cannot be presumed to have been aware of every item of prior art as would the |
| 4 | hypothetical person of ordinary skill in the art. But it must account for prior art |
| 5 | which it is aware. With respect to the spiral-pattern-omission feature, if Roubin is |
| 6 | aware of no closer prior art than Burmeister WO and Goicoechea '627, its simply |
| 7 | stating so may suffice. There is no such representation in Roubin's Motion 1. |
| 8 | Roubin apparently responds only to arguments made in Burmeister's |
| 9 | suggestion for interference, rather than establishes independently, as it should, |
| 10 | that the claims are patentably distinct from the count. That seriously undermines |
| 11 | the motion for which Roubin bears the burden of proof. |
| 12 | As is already noted above, the Board had given explicit notice to Roubin |
| 13 | that it may not restrict its analysis to only the prior art of record in either party's |
| 14 | involved application or patent but must address the level of ordinary skill in the |
| 15 | art as well as that prior art otherwise known to Roubin. (Paper 26). Roubin |
| 16 | makes no representation that it is unaware of any prior art which discloses the |
| 17 | spiral-pattern-omission feature. |
| 18 | G. Biocompatible Graft Covering |
| 19 | For claim 19 of Roubin '321, Roubin correctly notes that it comprises a |
| 20 | stent according to the count in combination with a biocompatible graft covering. |
| 21 | |
| 22 | The only disclosure of the biocompatible graft covering in Roubin's |
| 23 | specification is reproduced in its entirety below (Roubin '321 5:15-18): |
| 24 | The stent may also be coated with coverings of PTFE, dacron, or |

other biocompatible materials to form a combined stent-graft 1 prosthesis. 2 3 4 In arguing that implementing the biocompatible graft covering in 5 combination with the count would not have been obvious to one of ordinary skill in the art, Roubin specifically discusses only one reference - Goicoechea '627. 6 Roubin asserts that implementing the covering feature raises "additional, 7 independent design considerations . . . because of the function of the connecting 8 members." (Motion 18:21-24). 9 Goicoechea '627 discloses a biocompatible graft covering in combination 10 with an expandable stent. (Goicoechea '627 10:30-39). The count discloses an 11 12 expandable stent having connecting members preset with an elasticity to elongate 13 longitudinally to compensate for smaller longitudinal dimensions of expanded 14 annular elements. Notwithstanding the connecting elements with a preset 15 elasticity in the expandable stent of the count, there is at least a prima facie case of obviousness for one with ordinary skill in the art to implement the 16 biocompatible graft covering in the expandable stent of the count. After all, the 17 stent is for use within the body and Goicoechea clearly discloses the desirability 18 of using a biocompatible graft covering on such a stent. 19 20 That implementing the biocompatible-graft feature in combination with the 21 subject matter of the count would involve design considerations is expected. But that should be the beginning of Roubin's analysis, not the end. A person of 22 23 ordinary skill in the art is presumed to have skills apart from what the prior art 24 references explicitly say. KSR Int'l Co. 550 U.S. at 418. One with ordinary skill 25 in the art is also a person of ordinary creativity, and not an automaton. *Id.* at 421.

- 1 Roubin has not asserted, much less established, that implementing the
- 2 biocompatible-graft feature in the subject matter of the count would have been
- 3 beyond the level of ordinary skill in the art or unachievable by one with ordinary
- 4 skill in the art. Roubin also has not asserted or demonstrated that one with
- 5 ordinary skill would not have expected a successful implementation.
- Furthermore, claim 19 depends from claim 1 which serves as an alternative
- 7 in the count. Roubin points to nothing in its own disclosure which constitutes a
- 8 special way of implementing the biocompatible graft covering on a stent
- 9 including elongating connecting members to compensate for foreshortening.
- 10 That is a further indication that the implementation is within the level of ordinary
- 11 skill in the art.
- H. Same Length in the Expanded State and Compressed State
- 13 For claims 1-8, 12, 17, 20, 22, and 25 of Roubin '236, Roubin correctly
- 14 notes that these claims recite a stent having segments with varying diameter in
- the expanded state while the length of the stent remains the same in both the
- expanded and compressed states. (Motion 19:13-23). Roubin correctly notes
- 17 that this feature requires a stent to have no foreshortening between the
- 18 compressed and expanded states. (Id.). The count has no such requirement and
- we refer to it as the same-length feature.
- 20 Roubin argues that one of ordinary skill in the art would not have thought
- 21 to implement a stent wherein the length of the stent is the same in the expanded
- 22 and the compressed state, and further argues that the same-length feature would
- 23 not have been obvious in view of the count. (Motion 19:13-25).
- The argument is unpersuasive.

| 1 | Jang '743 teaches an expandable stent that has a substantially constant |
|----------------|---|
| 2 | unexpanded and expanded longitudinal length to help alleviate the foreshortening |
| 3 | of a stent from the compressed to the expanded state. (Jang '743 7:42-54; 9:10- |
| 4 | 65). It would have been at least prima facie obvious to one with ordinary skill in |
| 5 | the art to include that desirable feature within the subject matter of the count. |
| 6 | Roubin can rebut the prima facie case of obviousness by making a showing that |
| 7 | the combination would have been so technically complex that it would have been |
| 8 | beyond the level of ordinary skill to implement and that one with ordinary skill in |
| 9 | the art would not have expected to successfully complete the implementation. |
| 10 | However, Roubin has made no such showing. |
| 11 | That implementing the same-length feature of Jang '743 in the subject |
| 12 | matter of the count would have involved design considerations is expected. That |
| 13 | should be the beginning of Roubin's analysis, not the end. A person of ordinary |
| 14 | skill in the art is presumed to have skills apart from what the prior art references |
| 15 | explicitly say. KSR Int'l Co. 550 U.S. at 418. One with ordinary skill in the art |
| 16 | is also a person of ordinary creativity, and not an automaton. <i>Id.</i> at 421. Roubin |
| 17 | has not asserted, much less established, that the task of implementing the same- |
| 18 | length feature in combination with the subject matter of the count would not have |
| 19 | been achievable by one with ordinary skill in the art. |
| 20 21 22 | I. First Segment having a Plurality of Combined Adjacent Cells that Impart Greater Flexibility to the First Segment than the Second Segment |
| 23 | For claims 1-7 of Patent 6,106,548, Roubin correctly points out that they |
| 24 | recite a stent having a first segment with a plurality of combined adjacent cells |

- that impart greater flexibility to the first segment than to the second segment.
- 2 (Motion 19:28-20:1). The count has no such requirement and we refer to it as the
- 3 flexible-segment feature.
- 4 Roubin discusses Figures 11a and 11b of Burmeister WO (Motion 20:3-
- 5 13) but not that part of Burmeister WO teaching that connecting members are
- 6 removed from portions of the stent to form segments of different flexibility.
- 7 (Burmeister WO 12:11-16; Figures 10a-10d). Thus, Roubin's argument about
- 8 Burmeister WO is unpersuasive. Roubin also cannot show non-obviousness by
- 9 attacking references individually where the matter is based on a combination of
- prior art. *In re Keller*, 642 F.2d at 426. Here, the count is regarded as prior art.
- Also, Goicoechea '627 discloses an expandable stent having a segment formed of
- small hoops of unit width and a segment of intermediate hoops of twice unit
- width. (Goicoechea '627 9:20-33). The latter has more flexibility and each
- intermediate hoop has four adjacent small hoop cells. (*Id.*). Roubin's not
- discussing Goicoechea's disclosure in connection with the flexible-segment
- 16 feature also renders its argument unpersuasive.

17 Conclusion

- For all of the foregoing reasons, and considering collectively all of the
- 19 differences Roubin has identified for each claim with respect to the subject matter
- of the count, Roubin has not satisfied its burden of proof in showing that it is
- entitled to the relief requested, *i.e.*, to have claims 8, 10-12, 16-19, and 21-54 of
- 22 Roubin '321, claims 1-25 of Roubin '236, and claims 1-12 of Roubin '548
- 23 designated as not corresponding to the count.
- Roubin's Motion 1 is *denied*.

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